

**Notice of Allowability**

Application No.

08/260,536

Examiner

Emily Le

Applicant(s)

LORENCE ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/05/05, 11/10/05 and 1/04/2006.
2. ☒ The allowed claim(s) is/are 332-338, 342, 352, 367-374, 386-387, 392-397, 399 and 403.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

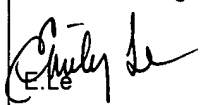
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 7/05/05, 11/10/05, 7/28/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_



James Housel  
Supervisory Patent Examiner  
Art Unit 1648

***Reason(s) for Allowance***

1. The broadest scope of the invention is directed at the intravenous administration of a pharmaceutical composition comprising live purified Newcastle Disease Virus, in an amount sufficient to cause tumor regression and in more than one dose, to a mammal having a tumor to treat said mammal of the tumor or cancer.
2. The above-summarized invention is free of the art. The Office is aware of the association between Newcastle Disease Virus and tumor treatments noted in the prior and present art. However, it is found that the instant invention is novel and unobvious from the teachings present in the prior art, which are included in the file history for this patent. It is found that that the prior art does not teach tumor regression in a mammal with a systemic, i.e., intravenous, administration of a pharmaceutical composition comprising live and purified Newcastle Disease Virus to said mammal. The prior art is directed at local administration, i.e., subcutaneous injection, of pharmaceutical compositions comprising attenuated Newcastle Disease Virus or unpurified Newcastle Disease Virus to influence tumor growth. Specifically, the prior art teaches the use of Newcastle Disease Virus as an adjuvant with viral oncolysates to induce an immune response against tumor antigens to inhibit tumor growth. Additionally, the art demonstrates an absence of antitumor activity with systemic administration of the virus. Moreover, the art notes that the systemic administration of the virus may actually be deleterious.

**Conclusion**

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
James Housel  
Supervisory Patent Examiner  
Art Unit 1648  
1/19/06

E.Le